

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B020603QH16		FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/000366	International filing date (day/month/year) 19.01.2004	Priority date (day/month/year) 31.01.2003	
International Patent Classification (IPC) or national classification and IPC A61K 31/09, 31/122, 45/00, 9/06, 9/10, 9/12, 9/70, A61P 3/02, 21/00, 43/00			
Applicant KANEKA CORPORATION			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000366

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000366

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application☒ claims Nos. 16-27

because:

☒ the said international application, or the said claims Nos. 16-27
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 16 to 27 pertain to a method for the treatment of the human body by means of therapy, and thus relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.☒ no international search report has been established for said claims Nos. 16-27☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished☐ does not comply with the standard

the computer readable form

☐ has not been furnished☐ does not comply with the standard☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000366

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-10, 14, 15	YES
	Claims	1-3, 11-13	NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: WO 98/07417 A1 (Kaneka Corp.), 26 February 1998

Document 2: JP 10-287560 A (Taisho Pharmaceutical Co., Ltd.), 27 October 1998

Document 3: JP 10-53520 A (Takeda Chemical Industries, Ltd.), 24 February 1998

Document 4: JP 7-330584 A (Taisho Pharmaceutical Co., Ltd.), 19 December 1995

Document 5: JP 7-330593 A (Taisho Pharmaceutical Co., Ltd.), 19 December 1995

Document 6: JP 2002-363073 A (Kabushiki Kaisha Kuressendo Corp.), 18 December 2002

Claims 1 to 3 and 11 to 13

The inventions that are set forth in claims 1 to 3 and 11 to 13 lack novelty and do not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 discloses a medicinal composition that comprises more than 20% by weight of a reduced coenzyme Q₁₀ as an active component, and further indicates that coenzyme Q₁₀ may be necessary in order to alleviate physical fatigue; that coenzyme Q₁₀ preparations can be

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

configured with a dissolved form, an emulsified form or a dispersed form; and that the bioavailability of a reduced coenzyme Q₁₀ is superior to that of an oxidized coenzyme Q₁₀.

The inventions that are set forth in claims 1 to 3 and 11 to 13 do not involve an inventive step in the light of documents 2 to 6 cited in the international search report.

Documents 2 and 4 to 6 disclose agents for reducing fatigue, which comprise an ubiquinone (corresponding to oxidized coenzyme Q₁₀) as the active component. On the other hand, document 3 discloses anti-fatigue agents comprising a compound represented by formula (I), which has a chemical structure similar to that of an ubiquinone, as an active component; therein, document 3 also indicates that it is possible to configure similar anti-fatigue agents from not only quinone-type (oxidized) species of ubiquinone, but also from hydroquinone-type (reduced) species of ubiquinone. Consequently, it would be easy for a person skilled in the art to attempt to determine what activity would result if a hydroquinone-type ubiquinone (i.e. a reduced coenzyme Q₁₀) were used as the anti-fatigue agent in the inventions that are disclosed in documents 2 and 4 to 6.

Claims 4 to 10, 14 and 15

The inventions that are set forth in claims 4 to 10, 14 and 15 do not involve an inventive step in the light of documents 1 to 6 cited in the international search report.

Document 1 indicates that reduced coenzyme Q₁₀s are useful for promoting recovery from fatigue. Meanwhile,

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000366

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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documents 2 to 6 disclose agents for reducing fatigue, wherein the active component is combined with other components which are useful for promoting recovery from fatigue, such vitamins, amino acids and anti-oxidizing agents. Therefore, it would be easy for a person skilled in the art to attempt to add components which are known to be useful for promoting recovery from fatigue to the invention that is disclosed in document 1, as appropriate.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000366

Box No. VI

Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2003-119127 A Kaneka Corp. [E, X]	23.04.2003	10.10.2001	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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